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Abstract

Background. Racial/ethnic minority patients are less likely than non-Latino white patients to participate in cancer clinical trials. A key barrier to participation is limited health literacy which is more common among minorities. At the organizational level, it is important that clinical trials sites become better equipped to recruit minority patients by expanding their organizational health literacy including language competency and outreach efforts. We explored the characteristics of clinical trial sites that are associated with these health literate behaviors.

Methods. We identified 353 breast clinical trials recruiting participants in 2006 from four states (California, Florida, Illinois, and New York) through the National Cancer Institute Physician Data Query system. From October 2008 to November 2009, we contacted one research team member (RTM) from each site for a telephone survey to assess the site's health literate characteristics.

Results. Of 233 RTMs who responded, 93% were female and 89% were US-born. Overall, 48% of sites offered supplementary trial information, 80% offered materials to assist with patient navigation and 45% reported outreach efforts. Lower percentages offered information in other languages while 65% offered professional interpretation services. Sites with >10% limited English proficiency (LEP) patients were more likely than their counterparts to offer consent forms (OR=3.13, 1.36-7.19) and supplementary information about trials in other languages (OR=2.52, 1.15-5.52). Sites with diverse patient populations (>10% Latino) were also more likely than less diverse sites to engage in outreach (OR=1.97, 1.07-3.60), to offer consent forms (OR=2.72, 1.38-5.36), supplementary information about trials (OR=2.58, 1.24-5.36), and materials to improve patient navigation (OR=2.50, 1.22-5.13) in other languages.

Conclusions. Efforts to recruit diverse participants were limited. Practice type and diversity of patient population were associated with sites' efforts to accommodate these characteristics, suggesting that sites were responsive to the needs of their patients when diversity was prevalent.

Keywords

cancer clinical trials; trial site environment; health literate organizations

Cover Page Footnote

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Health Literate Organizations: Are Clinical Trial Sites Equipped to Recruit Minority and Limited Health Literacy Patients?

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ABSTRACT

Background Racial/ethnic minority patients are less likely than non-Latino white patients to participate in cancer clinical trials. A key barrier to participation is limited health literacy which is more common among minorities. At the organizational level, it is important that clinical trials sites become better equipped to recruit minority patients by expanding their organizational health literacy including language competency and outreach efforts. We explored the characteristics of clinical trial sites that are associated with these health literate behaviors.

Methods We identified 353 breast clinical trials recruiting participants in 2006 from four states (California, Florida, Illinois, and New York) through the National Cancer Institute Physician Data Query system. From October 2008 to November 2009, we contacted one research team member (RTM) from each site for a telephone survey to assess the site's health literate characteristics.

Results Of 233 RTMs who responded, 93% were female and 89% were US-born. Overall, 48% of sites offered supplementary trial information, 80% offered materials to assist with patient navigation and 45% reported outreach efforts. Lower percentages offered information in other languages while 65% offered professional interpretation services. Sites with >10% limited English proficiency (LEP) patients were more likely than their counterparts to offer consent forms (OR=3.13, 1.36-7.19) and supplementary information about trials in other languages (OR=2.52, 1.15-5.52). Sites with diverse patient populations (>10% Latino) were also more likely than less diverse sites to engage in outreach (OR=1.97, 1.07-3.60), to offer consent forms (OR=2.72, 1.38-5.36), supplementary information about trials (OR=2.58, 1.24-5.36), and materials to improve patient navigation (OR=2.50, 1.22-5.13) in other languages.

Conclusions Efforts to recruit diverse participants were limited. Practice type and diversity of patient population were associated with sites' efforts to accommodate these characteristics, suggesting that sites were responsive to the needs of their patients when diversity was prevalent.

Keywords: Medicine, Public Health Sciences, Organizational Development, Cultural Competency

INTRODUCTION

Clinical trials provide the foundation for advances in cancer diagnostics and therapeutics and are the major channel for translating treatment-related discoveries in breast cancer care into clinical practice (Ford et al., 1990). Clinical trials provide a high standard of medical care and help to generate new information that helps future patients (American Society of Clinical Oncology, 2012). To ensure that the benefits and burdens of this research are distributed fairly among all breast cancer patients, it is important that minorities participate. However, despite recent efforts to increase the participation of African Americans and Latinos in cancer clinical trials (Alexander et al., 2000; G. Corbie-Smith et al., 2003; Ness et al., 1997; Tejeda et al., 1996), their enrollment remains lower than that of non-Latino Whites (Murthy et al., 2004).

Reasons for lower rates of minority participation in clinical trials are multifaceted and may be explained by past experiences of minority patients with medical research resulting in negative attitudes toward clinical trials due to historical discrimination (Giselle Corbie-Smith et al., 1999; Kaluzny et al., 1993; Snow, 1993). Limited health literacy and limited English proficiency (LEP) are other key barriers to clinical trial recruitment (Joseph et al., 2009; Lloyd et al., 2008), and minorities disproportionally have limited health literacy and are of LEP (National Center for Education Statistics, 2006).

In addition, physician characteristics such as specialty and amount of time spent in patient care impact clinical trial discussions, referral, and recruitment (Nguyen et al., 2005; Siminoff et al., 2000). A review of the provider's role in clinical trial participation suggests that lack of physician awareness of clinical trials is a barrier to enrolling patients. Patient accrual is also negatively affected by physicians' attitudes towards patient adherence to the study protocol, patient mistrust of research, and patient costs (Howerton et al., 2007). At the organizational level, lower rates of clinical trial participation among minorities can be in part attributed to the health care system failing to address these patients' informational needs at appropriate language and health literacy levels (Paasche-Orlow et al., 2007). This becomes especially apparent when assessing communication capabilities of the clinical trial site, e.g. the healthcare organization's ability to provide linguistically appropriate and accessible information.

Given the number and complexity of available cancer clinical trials, it can be difficult for patients, particularly minorities, those with limited health literacy and those of LEP, to determine their potential eligibility which, by extension, limits their participation in trials. Patients often struggle to understand and make decisions about research participation in the face of life-threatening illness, multiple treatment options, and long-term physical, psychological, and logistical concerns. In addition, not all facilities have bilingual personnel to assist with recruitment and retention (Giuliano et al., 2000), which may particularly affect Latinos for whom English is a second language (U.S. Department of Commerce Bureau of the Census, May 2001). Thus, addressing the challenges of limited health literacy and LEP populations represents a critical focus for advancing cancer trial participation among minorities and thus reducing health disparities.

Recognizing this, the Institute of Medicine (IOM) has identified health literacy as an urgent national priority area, emphasizing the critical role of the health care system in addressing the needs of patients with limited health literacy (Brach et al., 2012). The IOM has defined

"health literate organizations" as "institutions that support individuals in navigating the complexities of the health care system" (Brach et al., 2012). The *Health Literate Care Model* is based on the principles of "Health Literacy Universal Precaution" developed by AHRQ (DeWalt et al., 2010). This model postulates the need for health care providers to approach all patients with the assumption that health information may not be fully understood (DeWalt et al., 2010), and incorporates recommendations to help health care systems reduce the complexity of medical care and ensure that patients are able to succeed in the health care environment.

The Agency for Healthcare Research and Quality (AHRQ) developed a toolkit to assist organizations in becoming health literate (DeWalt et al., 2010), recognizing that health literacy-related outcomes are a function of both patient and health care system characteristics (Paasche-Orlow et al., 2006; Paasche-Orlow et al., 2007). This toolkit provides a framework for organizations to become more health literate (DeWalt et al., 2010), and suggests that language competency (both written and verbal communication) and outreach efforts by organization (e.g., the clinical trials sites) are key to creating a health literate organization that addresses the needs of minority and limited health literacy patients, particularly those with LEP. Little is known about the organizational characteristics that are associated with language competency and outreach efforts, and therefore likely to affect recruitment of minorities into clinical trials.

To extend the current state of knowledge in this area, our study explored the clinical trial site (organizational) characteristics (e.g., practice type, racial/ethnic diversity of patient population, language diversity of patient population and number of phase III trials offered) that were associated with health literate behaviors (e.g., language competency and outreach) among clinical trial sites in California, Florida, Illinois, and New York recruiting patients for breast cancer trials in 2006.

METHODS

As part of a Department of Defense-funded project, we identified 384 breast cancer clinical trials recruiting participants in 2006 from four states (California, Florida, Illinois, and New York) through the Physician Data Query (PDQ) from the National Cancer Institute website. These states were selected because of their large minority populations who were potentially eligible to participate in clinical trials. We identified all sites implementing these trials (n=353) and the research team members (RTMs) involved at each site. Trials were eligible for inclusion if they were: a) located in California, Florida, Illinois, or New York; b) conducted in 2006; c) related to breast cancer treatment; and d) funded by the National Institutes of Health (NIH) and/or a pharmaceutical company. General information about the clinical trials, as well as contact information for the sites where they were conducted was obtained from the PDQ. The websites of the involved institutions were also consulted to obtain more detailed contact information for the individuals involved in breast cancer clinical trials, hereafter referred to as RTMs.

Research assistants contacted one RTM from each site to complete a brief phone survey from October 2008 through November 2009. The survey was also available by mail, fax, or email, depending on preference. Verbal informed consent was obtained prior to the survey. All procedures were approved by the Committee on Human Research at the University of California San Francisco.

Measures

RTM characteristics

RTMs were asked to report their gender, country of birth, job title (clinical manager/coordinator, nurse, director/investigator, data manager/administrative personnel), and whether or not they spoke a language other than English.

Clinical trial site characteristics

RTMs were asked to describe their organization (e.g., practice type), and responses were grouped as follows; a) solo or group practice, b) public community health center/public hospital, c) VA, private or community based hospital, or d) University/medical school based practice/research or cancer institute. RTMs were also asked to estimate the percentages of their breast cancer patients who were Latina, Black or African American and had limited ability to communicate in English (limited English proficiency – LEP). These percentages were assessed continuously and dichotomized as ≥10% vs. <10%. For each site, we also obtained information on the number of phase III trials currently being conducted (responses were dichotomized into ≥3 vs. <3).

Health literate characteristics

Communication (written and verbal), and outreach efforts were assessed to capture the health literate characteristics of each trial site. We asked RTMs to report the availability, overall and in languages other than English, of consent forms, summaries of studies, frequently asked questions (FAQ) sheets about studies, directions to study site and appointment reminder cards. We also asked about the availability of professional interpreter services and whether the sites gave outreach presentations to community, social and service groups and churches and participated in community health fairs or cancer awareness days to recruit patients.

Communication (written)

Consent documents. Respondents were asked whether printed consent documents were available to patients in languages other than English (yes or no).

Supplementary information about clinical trials. Respondents were asked to indicate whether their organizations provided summaries of clinical trials and frequently asked questions (FAQ) sheets to patients overall (yes or no) and in a language other than English (yes or no). In both instances, if a respondent answered yes to both questions (e.g., summaries and FAQ sheets), their site was considered to offer supplementary information about clinical trials (overall or in other languages)

Materials to facilitate recruitment into clinical trials. Respondents were asked to indicate whether their organizations provided directions to the study site or appointment reminder cards to patients overall (yes or no) and in a language other than English (yes or no). If a respondent answered yes to either of these questions (e.g., directions or appointment reminder cards), their site was considered to offer materials to improve patients' navigation into clinical trials (overall or in other languages).

Communication (verbal)

Professional interpretation services. Those sites offering professional onsite interpreters, professional interpreter services by telephone, or professional video interpreter services were considered to have professional interpretation services available.

Outreach

Outreach efforts. Respondents were asked about their sites' general recruitment strategies, including: presentations to community, social service groups, and churches and

participation in community health fairs or cancer awareness days. If a respondent answered yes to both of these recruitment strategies, their site was considered to engage in outreach efforts.

Analysis

Descriptive statistics were used to profile RTM characteristics, clinical trial site characteristics and health literate characteristics of the sites. We explored associations between individual clinical trial site characteristics (e.g., practice type, number of phase III trials, ≥10% Latina patients, ≥10% African American patients and ≥10% LEP patients) and health literate characteristics (e.g., communication and outreach). For each association, we used logistic regression analysis to estimate odds ratios [OR] and 95% confidence intervals [CI] and conducted all analyses in Stata Version 11.2. All comparisons were adjusted for state and practice type (with the exception of the practice type analyses which were adjusted only for state).

RESULTS

Sample characteristics. Of the initial 353 clinical trials sites selected, 85 were ineligible (68 sites were excluded because they had the same staff and practices as another site that had already completed the survey, 7 sites no longer conducted clinical trials, 1 was under new management, 4 did not enroll breast cancer patients, and 5 never participated in clinical trials). The remaining 268 were contacted for interviews. Twenty-two sites refused to participate, four no longer employed RTMs and nine were never reached. This yielded 233 completed interviews for a response rate of 87%.

Descriptive analysis

RTM characteristics. The majority of RTM respondents were female and born in the United States (see Table 1). More than half of respondents identified themselves as the clinical manager or clinical coordinator at their site, while 24% were nurses, 10% identified themselves as the Director or a trial Investigator and 10% identified themselves as the data manager or administrative personnel. Approximately one-quarter of respondents spoke another language in addition to English.

Clinical trial site characteristics. Thirty-seven percent of trial sites were located in California, 23% in New York, 20% in Illinois and 20% in Florida (see Table 1). The majority of sites were solo or group practices, while more than one-quarter were public or community health centers or hospitals, 20% were university or teaching hospitals or research/cancer institutes and less than 10% were VA, private or community hospitals. On average, sites reported that 13% of their breast cancer patients were African American, 15% were Latina, and 8% were LEP. Just over half of the sites had 3 or more Phase III trials underway.

Table 1. Research team member (RTM) and clinical trial site characteristics (N=233)

	n %[a]
RTM Characteristics	
Female	215 (92.7)
Born in the U.S.	201 (88.6)
Job title	
Clinical manager/coordinator	131 (56.5)
Nurse	55 (23.7)
Director/Investigator	22 (9.5)
Data manager/administrative personnel	24 (10.3)
Speaks another language	60 (25.9)
Clinical trial site characteristics	
State	
California	87 (37.3)
Illinois	47 (20.1)
New York	53 (22.8)
Florida	46 (19.7)
Type of Practice	
Solo or group practice	105 (45.1)
Public community health center/hospital	63 (27.0)
VA, private or community hospital	21 (9.0)
University/teaching hosp/research or cancer institute	44 (18.9)
Patient population	
% African American (mean ± SD)	12.5 ± 16.1
% Latinos (mean ± SD)	15.2 ± 18.2
% with limited English proficiency (mean ± SD)	8.4 ± 14.4
Number of Phase III Clinical trials	
≤2	111 (47.6)
≥3	122 (52.4)

[a]Percentages based on non-missing values

Health literate characteristics. Seventy-two percent of sites offered consent documents in languages other than English (see Table 2). Slightly less than half of sites (48%) offered supplemental information about clinical trials, including both summaries of studies and FAQ sheets, and only 22% offered these materials in languages other than English. While the majority of sites (80%) offered materials to facilitate recruitment into clinical trials (directions to study site or appointment reminder cards), only 26% offered either of these materials in other languages. Sixty-five percent of sites offered professional interpretation services. Less than half of sites engaged in outreach efforts including both presentations to community, social and service groups and churches and participation in community health fairs or cancer awareness days.

Table 2. Health Literate Characteristics of Clinical Trial Sites (N=233)

	Available for English-speaking patients n (%)	Available for non-English-speaking patients n (%)
COMMMUNICATION (WRITTEN AND VERBAL)		
Consent forms	23 (100)	167 (71.7)
Supplementary information about clinical trials (both types available)	112 (48.1)	52 (22.3)
Summaries of studies	153 (65.7)	78 (33.5)
Frequently asked questions sheets about studies	144 (61.8)	79 (33.9)
Any materials to facilitate recruitment into clinical trials	186 (79.8)	61 (26.3)
Directions to study site	105 (45.1)	39 (16.8)
Appointment reminder cards	161 (69.1)	41 (17.6)
Professional interpretation services	n/a	151 (64.8)
OUTREACH		
Outreach efforts (both types used)	105 (45.1)	n/a
Presentations to community, social and service groups, churches	117 (50.2)	n/a
Participation in community health fairs or cancer awareness days	160 (68.7)	n/a

Multivariable analyses

Health literate characteristics (overall) (Table 3)

Supplementary information about clinical trials. None of the clinical trial site characteristics we explored were significantly associated with offering supplementary information about clinical trials (summaries of studies and FAQs)

Materials to facilitate recruitment into clinical trials. Compared to solo or group practice sites, sites within public or community health centers or hospitals (OR=0.28, 0.13-0.64), and VA, private or community hospitals (OR=0.29, 0.09-0.94) were less likely to offer materials to improve patient navigation to trials. Trial sites with patient populations of ≥10% LEP were also less likely to offer these materials (OR=0.46, 0.21-0.99).

Outreach efforts. Compared to solo or group practice sites, university/teaching hospitals and research/cancer institutes were more likely to engage in outreach efforts (OR=2.20. 1.03-4.70), as were sites with patient populations of ≥10% Latina compared to their counterparts (OR=1.97, 1.07-3.60).

Table 3. Adjusted Odds Ratios: Availability of services according to site characteristics (n=233)

	COMMUNICATION (Written)		OUTREACH
	Supplementary information about clinical trials OR (95% CI)	**Any materials to facilitate recruitment into clinical trials OR (95% CI)**	**Outreach efforts OR (95% CI)**
Type of practice[a]			
Solo or group practice	*ref*	*ref*	*ref*
Public community health center/hospital	1.02 (0.54-1.92)	**0.28 (0.13-0.64)[2]**	1.80 (0.91-3.29)
VA, private or community hospital	0.60 (0.22-1.60)	**0.29 (0.09-0.94)[3]**	1.19 (0.44-3.22)
University/teaching hosp/research or cancer institute	0.66 (0.31-1.40)	0.40 (0.15-1.07)	**2.20 (1.03-4.70)[3]**
Number of phase III clinical trials[b]			
≤ 2 phase III trials	*ref*	*ref*	*ref*
≥3 phase III trials	1.55 (0.90-2.66)	1.43 (0.73-2.83)	1.07 (0.62-1.85)
Percent of Latinas in patient population[b]			
<10%	*ref*	*ref*	*ref*
≥10%	1.64 (0.91-2.96)	0.99 (0.47-2.07)	**1.97 (1.07-3.60)[3]**
Percent of African Americans in patient population[b]			
<10%	*ref*	*ref*	*ref*
≥10%	1.10 (0.62-1.96)	1.33 (0.63-2.81)	1.04 (0.58-1.86)
Percent of patients who are LEP[b]			
<10%	*ref*	*ref*	*ref*
≥10%	1.37 (0.72-2.62)	**0.46 (0.21-0.99)[3]**	1.42 (0.74-2.73)

[a] Analyses adjusted for state

[b] Analyses adjusted for state and practice type

[1]p<0.05; [2]p<0.01; [3]p<0.05

Health literate characteristics (services available in other languages) (Table 4)

Consent forms in other languages. Trial sites with patient populations of ≥10% Latina and ≥10% LEP were more likely than their counterparts to provide consent forms in other languages (OR= 2.49, 1.28-4.85 and OR=3.13, 1.36-7.19 respectively).

Supplemental information about clinical trials in other languages. Trial sites with patient populations of ≥10% Latina and ≥10% LEP were more likely than their counterparts to offer supplemental information about clinical trials in other languages (OR=2.58, 1.24-5.36 and OR=2.52, 1.15-5.52 respectively).

Materials to facilitate recruitment into clinical trials, in other languages. Trial sites with patient populations of ≥10% Latina were more likely than their counterparts to offer materials in other languages to improve access to care (OR=2.50, 1.22-5.13).

Professional interpretation services available. Compared to solo or group practice sites, sites within public or community health centers or hospitals (OR=7.45, 3.32-16.8), VA, private or community hospitals (OR=3.59, 1.20-10.7) and university/teaching hospitals and research/cancer institutes (OR=4.22, 1.81-9.87) were more likely to provide professional interpretation services.

Table 4. Adjusted Odds Ratios: Availability of services in other languages, according to site characteristics (n=233)

	COMMUNICATION			
	(Written) Consent forms in other languages OR (95% CI)	**(Written)** Supplementary information about clinical trials, in other languages OR (95% CI)	**(Written)** Any materials to facilitate recruitment into clinical trials, in other languages OR (95% CI)	**(Verbal)** Professional interpretation services OR (95% CI)
Type of practice[a]				
Solo or group practice	*ref*	*ref*	*ref*	*ref*
Public community health center/hospital	0.76 (0.38-1.52)	1.49 (0.70-3.18)	0.96 (0.46-2.03)	**7.45 (3.32-16.8)[1]**
VA, private or community hospital	0.70 (0.25-1.90)	0.99 (0.25-3.94)	1.45 (0.49-4.31)	**3.59 (1.20-10.7)[3]**
University/teaching hosp/research or cancer institute	1.11 (0.47-2.58)	1.35 (0.54-3.37)	1.14 (0.50-2.64)	**4.22 (1.81-9.87)[2]**
Number of phase III clinical trials[b]				
≤ 2 phase III trials (ref)	*ref*	*ref*	*ref*	*ref*
≥3 phase III trials	0.70 (0.39-1.27)	1.05 (0.54-2.04)	0.82 (0.45-1.51)	1.79 (0.98-3.28)
Percent of Latinas in patient population[b]				
<10% (ref)	*ref*	*ref*	*ref*	*ref*
≥10%	**2.49 (1.28-4.85)[2]**	**2.58 (1.24-5.36)[3]**	**2.50 (1.22-5.13)[3]**	1.83 (0.93-3.62)
Percent of patients who are LEP[b]				
<10% (ref)	*ref*	*ref*	*ref*	*ref*
≥10%	**3.13 (1.36-7.19)[2]**	**2.52 (1.15-5.52)[3]**	2.02 (0.98-4.13)	1.99 (0.92-4.30)

[a] Analyses adjusted for state

[b] Analyses adjusted for state and practice type

[1]p<0.05; [2]p<0.01; [3]p<0.05

DISCUSSION

Patient and physician-level barriers to recruitment of minority patients into clinical trials have been well described but less is known about the organizational characteristics that are associated with language competency and outreach efforts, and therefore likely to affect recruitment of minorities into clinical trials. Characteristics of the clinical trial environment can influence whether or not minority, LEP, and limited health literacy patients participate in cancer clinical trials (Brach et al., 2012). As recognized by the Agency for Healthcare Research and Quality (AHRQ), language competency (written and verbal) and outreach efforts by clinical trial sites are necessary components for creating health literate organizations that are equipped to address the needs of minority and limited health literacy patients (DeWalt et al., 2010). The lack of language competency and outreach to these patients on the part of cancer clinical trial sites may explain in part the lower rates of trial participation documented in these groups (Alexander et al., 2000; G. Corbie-Smith et al., 2003; Murthy et al., 2004; Ness et al., 1997; Tejeda et al.,

1996). Overall, the clinical trial sites we examined made limited efforts to recruit ethnically and linguistically diverse participants.

Information transfer within the informed consent process and full disclosure of information regarding content and delivery of treatment in a clinical trial are believed to be important predictors of recruitment of patients into trials (Wright et al., 2002). While the majority of clinical trial sites offered consent forms to patients in languages other than English , consent forms are considered difficult to understand and interpret (Cornett, 2009; Davis et al., 2002; Lorenzen et al., 2008) and may not sufficiently enable patients to make informed decisions about participation. Offering materials that provide supplemental information about clinical trials can be essential to encouraging participation. Short summaries of trials and FAQ sheets may assist in making consent forms more comprehensible, allowing patients to make fully informed decisions about participation (Institute, 2013). However, less than half of sites offered any supplemental materials to patients, and even fewer offered these materials in languages other than English. Of note, language competency, including the availability in other languages of consent forms and supplementary information about clinical trials, was greatest among sites serving diverse populations with large proportions of Latinos and LEP patients. The increased availability of short summaries and FAQ documents in other languages at sites with more diverse populations suggests that these sites are responding to the needs of their patient populations (e.g., Latinas and LEP patients) by providing materials in other languages.

While most sites offered materials including directions to the study site and appointment reminders to facilitate patients' navigation to clinical trials, hospitals were less likely to do so than solo practices, as were sites with ≥10% LEP patients. In addition, very few sites offered these materials in other languages. However, our results suggest that if these materials were available at a site, those sites with more LEP patients were more likely to offer the materials in other languages.

The use of professional interpretation services among LEP patients is associated with improved quality of clinical care (Flores, 2005; Karliner et al., 2007), and is also likely to facilitate recruitment of these patients into clinical trials. However, less than two-thirds of clinical trial sites offered professional interpretation services. Solo and group practices were less likely than other sites to do so. Resources available to larger institutions may partially explain the discrepancy. With larger patient populations, the cost-effectiveness of interpretation services may be greater due to economies of scale or shared resources across sites. In addition, the federal government mandates health care providers who receive federal funding to provide language interpretation services to their LEP patients (Blanchfield et al., 2011; Jacobs et al., 2006) and larger institutions may be more likely to receive federal funding. Another potential explanation is that solo and group practices had the least diverse patient populations in our study.

Outreach efforts are also a critical component of recruiting clinical trial participants, particularly for difficult-to-reach populations including racial/ethnic minorities and those with limited health literacy. Less than half of the clinical trial sites we studied engaged in community outreach. University/teaching hospitals and research or cancer institutes were more likely than solo or group practices to engage in outreach, as they may have been better equipped to do so, given greater resources. Sites with more diverse patient populations were also more likely to engage in outreach efforts. The latter finding provides further evidence that sites appear to be responding to the needs of their patient populations by engaging in outreach efforts to target difficult-to-reach individuals (e.g., Latinas).

Several limitations to our study are worth noting. We were not able to interview RTMs from all sites identified. If site characteristics differed between RTM respondents and non-respondents, our findings may not be generalizable. Findings may also not be representative of practices or behaviors in less diverse areas of the country since we selected trials conducted in states with large minority populations. Language competency may be even poorer in less diverse areas of the country. We did not assess the quality of materials translated into other languages or their literacy level. Thus, the supplementary information provided about clinical trials may have been written at a high literacy level. In addition, we relied on key informant RTMs from each clinical trial site to answer questions about language competency and outreach. It is possible that the person interviewed might not have had all of the necessary information to answer these questions. However, we attempted to interview RTMs who were intimately involved in all aspects of the clinical trials being conducted at their site.

Finally, data were cross sectional. As a result, we are unable to establish whether clinical trial site characteristics influenced the patient population served, or whether trial sites adapted their recruitment efforts to fit the needs of their specific patient population. Sites that do not serve many LEP patients may have limited incentives or demand to provide patient materials and study information in other languages. However, if these sites were to improve their language competency, perhaps they would attract more culturally and linguistically diverse patients.

CONCLUSION

Language competency is an elemental characteristic of health literate organizations. Without language appropriate materials or professional interpreter services, clinical trials sites rely on ad hoc interpretation that may be imprecise and misleading. Improving cultural and language competency is a desirable goal that can be strived for and potentially achieved by most clinical trial sites. The failure to do so undermines the clinical trial site's outreach and recruitment efficacy and further undercuts national efforts to diversify the pool of clinical trial participants (e.g. ENACCT, IMPACT, etc.). Our study identifies gaps in language competency and outreach efforts at the organizational level, and therefore, gaps in responsiveness to the most basic health literacy needs of patient populations at clinical trial sites across the United States.

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